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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,511	01/19/2001	Sean A. McCarthy	10147-65 (MPI2000-537OMNI	9759

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MILLENNIUM PHARMACEUTICALS, INC.
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CAMBRIDGE, MA 02139

EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,511	MCCARTHY ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,12,31 and 44-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 12, 31 and 44-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/16/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's amendment filed on 16 December 2004 is acknowledged and entered. Following the amendment, claims 1, 12 and 44 are amended.

Currently, 1-7, 12, 31 and 44-46 are pending, and under consideration.

Withdrawal of Objections and Rejections:

The rejection of claim 44 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7, 12, 31 and 44-46 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by a credible, substantial, specific, or well-established utility, for the reasons of record set forth in the previous Office Actions mailed on 23 April 2003, on 04 November 2003, and 14 June 2004.

Applicants argument filed on 16 December 2004 has been fully considered, but is not deemed persuasive for reasons below.

At page 7 of the response, the applicant argues that the application as filed has a well-established utility; that the inventors not only identified the TANGO405 as a C-type lectin family member, they had shown that TANGO405 was greatly homologous (89%) to murine dectin-2, which had been cloned in 1999, and was *believed to be* involved in the immune response; and that based on such, applicants asserted in the specification that human and murine TANGO405 are also involved in activating or inhibiting one or more types of lymphocytes, inflammatory responses, and other components of the immune responses. This argument is not persuasive because mere cloning of murine dectin-2 is not sufficient to confer a patentable utility for the molecule as it is still unclear what it can be used for. In fact, the assertion that murine dectin-2

was *believed to be* involved in the immune response, or in *activating or inhibiting* one or more types of lymphocytes clearly indicates no specific and substantial utility has been established for the murine dectin-2 as immune response encompasses many types of responses with distinct natures, and *activating or inhibiting* are mutually exclusive utilities, and both cannot be true. Such a statement of all options including opposing options is not the evidence for supporting a specific and substantial utility. Thus, there has been no patentable utility even established for the murine dectin-2. Therefore, the assertion that the present TANGO405 has a well-established utility based on its sequence homology to the murine dectin-2 is void. Further, *even if* the murine dectin-2 had "a well-established utility", it cannot be used to support a specific and substantial utility for the reasons as addressed in the previous Office Action mailed on 23 April 2003. Furthermore, as addressed in the Office Action mailed on 14 June 2004, prior art has established that C-type lectins exhibit diverse functions with biological significance, as such, even though all C-type lectins share some common sequence structures, it does not mean that they share similar functional properties. Therefore, established utility for a known member of the family (if applicable) cannot be automatically applied for a previously unknown member of the same family.

At pages 8-9 of the response, the applicant argues that applicants have asserted a specific, substantial and credible utility as the inventors had cloned a human C-type lectin having significant structure similarity to murine dectin-2, and therefore, useful in modulation of the immune response; that a peer reviewed publication by Kanazawa et al. confirms that TANGO405 is the human orthologue of murine dectin-2; and that murine dectin-2 plays a role in the mediation of UV-induced immunosuppression (by Aragane et al.), which, thereby, corroborates applicants assertion that TANGO405 plays a role in modulating immune response. This argument is not persuasive because, as addressed in the last Office Action, the main issue is not whether the present TANGO405 is a member of C-type lectin family, or a human orthologue of murine dectin-2, rather, the issue is that the function of C-type lectins is known in the art to be diverse and *not predictable* merely based upon the sequence homology. Therefore, as addressed above, an established utility for a known member of the family cannot be automatically applied for a previously unknown member of the same family. The present application does not disclose any functional property or biological significance that is *directly associated with the human*

TANGO405. As such, significant further research and experimentation are required in order to identify functional property or biological significance of the claimed TANGO405, and to reasonably confirm a "real world" context of use thereof, which, however, are part of the act of invention, and until it has been undertaken, the asserted utilities of claimed invention are not considered substantial.

At pages 9-10 of the response, the applicant repeated the argument present in the previous response and above that the examiner has not made an effective prima facie showing of lack of utility, and the examiner, according to MPEP, must establish that it is more likely than not that a person skilled in the art would not consider credible and specific and substantial utility asserted by the applicant for the claimed invention; that applicants had demonstrated that the facts of the present case were very similar to those exemplified in Example 10 of the Utility Guidelines (DNA ligases); that TANGO405 is the human orthologue of murine dectin-2, which is involved in the mediation of UV-induced immunosuppression. This argument is not persuasive because the matter is not that it is *more likely than not* that applicants assertion of utility is not considered specific and substantial, the matter is that the present application never discloses any specific and substantial utility directly and specifically associated with the claimed TANGO405. With respect to the case of DNA ligases in Example 10 of the Utility Guidelines, as addressed in the previous Office Action, in the enzyme world, functional property is much more predictable based on sequence homology. In contrast, the art has established that members of C-type lectin are extremely diverse with respect to their functional properties. As such, Example 10 in the Utility Guidelines does not apply in the instant situation.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 12, 31 and 44-46 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the previous Office Actions mailed on 23 April 2003, on 04 November 2003, and 14 June 2004.

Applicants argument filed on 16 December 2004 has been fully considered, but is not deemed persuasive for reasons above.

Furthermore, *even if* the specification taught how to use human TANGO405, enablement would remain not being commensurate in scope with claim 1, and the dependent claims 3-7, 12, 45 and 46, for the reasons of record set forth in the previous Office Actions, paper No. 17, mailed on 23 April 2003, and on 04 November 2003.

Conclusion:

No claim is allowed.

Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
3/30/05